Message

From: McNally, Robert [Mcnally.Robert@epa.gov]
Sent: 2/7/2017 10:33:51 PM
To: Milewski, Elizabeth [Milewski.Elizabeth@epa.gov]; Hartman, Mark [Hartman.Mark@epa.gov]; Leahy, John [Leahy.John@epa.gov]; Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]; Wozniak, Chris [wozniak.chris@epa.gov]; Kough, John [Kough.John@epa.gov]
Subject: RE: update on Oxitec

Thanks

I understand the trade-off, but given the public interest in GE, I would recommend we follow the transparency approach. Having said that, we would not go out of our way beyond what we normally do to broadcast the public comment period.

From: Milewski, Elizabeth
Sent: Tuesday, February 07, 2017 5:25 PM
To: McNally, Robert <Mcnally.Robert@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>; Leahy, John <Leahy.John@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Wozniak, Chris <wozniak.chris@epa.gov>; Kough, John <Kough.John@epa.gov>
Subject: RE: update on Oxitec

I think they are talking about actually working on the assessment. I doubt they could stomach the idea of us publicly announcing we were doing the review before FDA said it is not a new animal drug.

However, my understanding is that the NOR for an EUP can be somewhat discretionary? If yes discretionary, for this case 2 public goods are in opposition and would have to be weighed against each other. On the one hand, we would want the public to know we are now the agency who has taken up the responsibility. It is a pretty big deal. So for transparency we should do an NOR. On the other hand, this is a public health emergency and this product may be one really good means of controlling the primary carrier of the Zika virus. A mitigating consideration is the way the testing must be done – in the field with the testing opportunity coming around maybe only once a year. So if we miss the testing window, the company may have to wait a whole year. The Zika may have spread further into the US in that time and more people might be affected over the course of a year. So maybe weighing lives versus transparency.

Ex. 5 Deliberative Process (DP)

From: McNally, Robert
Sent: Tuesday, February 07, 2017 4:32 PM
To: Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>; Leahy, John <Leahy.John@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Wozniak, Chris <wozniak.chris@epa.gov>; Kough, John <Kough.John@epa.gov>
Subject: RE: update on Oxitec

Interesting. I did not get a chance to see this before the call. Since we have a Notice of Receipt, and a public comment period, for an EUP, is OGC saying that we can go through all of that while we were waiting for FDA to wrap up? Having the public involvement seems odd, if this is all sort of draft.

From: Milewski, Elizabeth
Sent: Tuesday, February 07, 2017 12:56 PM
To: McNally, Robert <Mcnally.Robert@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>; Leahy, John <Leahy.John@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Wozniak, Chris <wozniak.chris@epa.gov>; Kough, John <Kough.John@epa.gov>
Subject: RE: update on Oxitec

Hi, Bob. I just got off the phone with Ben on the question of whether we could start doing a "draft EUP" with Oxitec before FDA officially says that mosquitoes for population control are not new animal drugs and thus are in EPA's bailiwick. He says he talked to Scott Garrison and Chris K about whether that might be possible in light of appropriations questions. Both Scott and Chris K felt that in this circumstance the argument supporting our going forward with a draft EUP would be good government policy. So if Oxitec came in to start the process, we could work on the EUP, and when FDA declared officially that mosquitoes for population control are not new animal drugs, the company could then pay the PRIA fee, etc. He likened the situation to a relay race. When the runner comes in with the baton, the person receiving the baton cannot be standing still.

I agree I should put into the agenda a time for Oxitec to lay out their goals, and will do so. Makes sense – I started off my chat with Camilla this morning in the same way – asking her what they wanted.

I will include somewhere – annotation maybe? – that we need to bring up the likelihood of a SAP somewhere along the line.

About accepting foreign generated data to support a registration, I will start working on that. But it may be more complicated than I can resolve before Thursday. However, if we do start on a draft EUP – that whole issue might be resolved during our work on the EUP. Assuming I understood Mike correctly, that the question of the acceptability of foreign generated data is not as important for supporting issuance of an EUP. I will defer to Mike on that.

I am not sure that at the end of the day we would want to hand this agenda to Oxitec or even to FDA – it is more a way for me to organize the meeting so that it is productive. Actually simply thinking about the agenda has been helpful already to me.

From: McNally, Robert
Sent: Tuesday, February 07, 2017 12:10 PM
To: Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>; Leahy, John <Leahy.John@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Wozniak, Chris <wozniak.chris@epa.gov>; Kough, John <Kough.John@epa.gov>
Subject: RE: update on Oxitec

Thanks. Yes, I think that we will need to hear from FDA on their efforts. That would be important. They can't sit on their hands.

Again, I think Oxitec needs to kick off the meeting with what they are interested in covering, so both FDA and EPA can be most helpful.

We also need to discuss some sense of what data are needed for a section 3, and where it is from (Cayman Island?) etc. I am not looking for absolute certainty by Thursday, but we can't continue to punt when that is asked, as I am sure Keith will do. They may ask: "What else beyond what we are/may be doing for FDA, do you need us to do to get a Section 3 Registration?" Would we have a separate pre-submission meeting with them later in year??

Also, we need to indicate our sense that an SAP would likely be part of our section 3 process, and what science issues that would entail, given the novelty of the technology. We would highlight that the SAP would be generic to the novel issues, and maybe a product specific SAP, too.

Having said that, some kind of limited, time limited section 3 registration may be appropriate without an SAP, conceivably.

Since Rick may attend, we should send him a note summarizing what we will say and how we plan for the meeting to go. We all need to be on the same page.

Thoughts On this?

Bob

From: Milewski, Elizabeth
Sent: Tuesday, February 07, 2017 11:53 AM
To: McNally, Robert <Mcnally.Robert@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>; Leahy, John <Leahy.John@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Wozniak, Chris <wozniak.chris@epa.gov>; Kough, John <Kough.John@epa.gov>
Subject: update on Oxitec

Hi, Bob. I spoke with Camilla Beach this morning. Keith Matthews was also on the line. He is now once again counsel for them.

Looks like my original agenda is what Camilla wants from the meeting. As you suggested, I should put time on the agenda for FDA's opportunity to inform the Thursday meeting as to where they are with their process. As we will be talking with FDA this afternoon, can we ask them whether they are comfortable with giving a brief update of where they are in their process at the Thursday meeting with Intrexon? (Camilla tells me Oxitec hopes to have their revised submission of the amendment to the EA request at FDA by the end of February). If FDA is willing to share, I will insert time for them on the agenda.

I will be trying to put together a best-guess time-line for the various transfer-of-jurisdiction options this afternoon and tomorrow. Don't know in advance if it will be something worth sharing with others – have to see if I can develop something acceptable within EPA. Given the amount of emphasis Camilla and Keith put on data requirements in this morning's phone call, I am guessing that Keith is thinking about suggesting the option of going for a section 3 directly without going through an EUP might be in play. So, it would seem important to include in our presentation information on section 3 and its requirements. This also brings up the question of how much, if any, of foreign-generated data can be used to support a section 3 – a question we likely need to resolve soon. However, we can punt on that at the Thursday meeting. Camilla tells me that all the data for the foreign trials has appeared in the published literature. She will send files to us.

I have a call in to Ben letting him know that Keith intends to attend the Thursday meeting as Intrexon legal counsel. They may also bring their FDA attorneys if they can work it out. So hopefully Chris K and Ben can attend. I hope to chat with Ben today about the other issues we discussed yesterday, e.g., what can happen at EPA in the time between FDA's decision on the amended EA and FDA issuance of its final guidance 236. Assuming there actually is any time. With the FDA comment period on GFI 236 closing on February 21 and Oxitec hoping to submit their amended EA request by the end of February, it looks like FDA might have some options.

On a last note – Camilla tells me that although they would like to start their field trial prior to mid-May 2017, they intend to begin the trial whenever they get permission to proceed. So the window for starting testing would appear to extend from February through October. At least that is my guess from what was said in the conversation. Mosquito population numbers form a bell curve from February through November. They prefer earlier testing because it is easier technically

to test when the population is lower; however they can test at any point in the curve including at the peak, it is just more complicated to do so when mosquito numbers are high.

I will phone in to the FDA/EPA call this afternoon.